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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

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|---|---|
| FREDERICK and MyLINDA KING, parents and guardians ad litem for JORDAN KING, a minor child; BETTY STAFFORD, parent and guardian ad litem for JERRY N. STAFFORD III, a minor child; BONNIE STIERNA and STEVE STIERNA, parents and guardians ad litem for JOSIE STIERNA, a minor child; MARK LINDSEY and LIEN VU, parents and guardians ad litem for LORENZO QUOC ANH LINDSEY, a minor child; and DIANE DOGGETT and GARY FAGELMAN, parents and guardians | CV 01-1305-AS<br><br>STATEMENT OF INTEREST SUBMITTED BY THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES |

STATEMENT OF INTEREST BY HHS

ad litem for AUGUST FAGELMAN,

Plaintiffs,

On behalf of themselves and all others similarly situated,

vs.

AVENTIS PASTEUR, INC., individually and as successor in interest to Connaught Laboratories, Inc.; PASTEUR MERIEUX; PASTEUR MERIEUX CONNAUGHT; GLAXOSMITHKLINE, individually and as successor in interest to Smithkline Beecham Corp.; MERCK & COMPANY, INC.; ABBOTT LABORATORIES; AMERICAN HOME PRODUCTS, dba WYETH LABORATORIES, INC., dba WYETH, dba WYETH-AYERST, dba WYETH-AYERST LABORATOARIES, dba WYETH LEDERLE, dba WYETH LEDERLE VACCINES, aka LEDERLE LABORATORIES; and BAXTER INTERNATIONAL, INC., individually and as successor in interest to North American Vaccine, Inc., and ELI LILLY & COMPANY, INC.; and BEVERLY WITTKOPP, and LORI GILMARTIN, and WALTER BUHL,

Defendants.

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## MISCELLANEOUS

## I. STATEMENT OF INTEREST OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

The interest of the United States, through the Department of Health and Human Services (HHS), in this matter is to ensure the proper administration of the National Vaccine Injury Compensation Program ("Program"), the responsibility for which resides with the Secretary of HHS. See 42 U.S.C. §§ 300aa-10 to 300aa-34 (the "Act" or "Vaccine Act"). HHS must assert its views in this case for two compelling reasons. First, Plaintiffs have filed a declaration purporting to state that HHS has refused to contest the jurisdiction of this Court to resolve claims alleging thimerosal is an "adulterant" or "contaminent" and, therefore, outside the scope of the Program and the exclusive jurisdiction of the U.S. Court of Federal Claims. This is emphatically not the case as HHS sets forth in this Statement of Interest. Second, the resolution of the jurisdictional issues presented will directly impact the Secretary's ability to exercise his responsibilities in administering the Program. Specifically, should Plaintiffs prevail in forcing the finding they urge, the U.S. Court of Federal Claims would be deprived of its exclusive original jurisdiction over many claims required to be filed in that forum and adjudicated under the Program. Such a finding would undermine not only the words, but also the purpose, of the Act.

## II. AUTHORITY TO FILE

This brief is filed pursuant to 28 U.S.C. § 517, which authorizes the Department of Justice to attend to the interests of the United States in any suit pending in a court of the United States, or of any State.

## III. SUMMARY OF THE ARGUMENTS

Under the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 -

300aa-34, the U.S. Court of Federal Claims has exclusive original jurisdiction over claims of "vaccine-related injuries"; however, the Court of Federal Claims is not given exclusive jurisdiction where an "adulterant" or a "contaminant" is intentionally added to a vaccine. The linchpin of Plaintiffs' argument is their erroneous assertion that thimerosal, used as a preservative in vaccines, is an "adulterant" or "contaminant." Plaintiffs' argument is merely an attempt to evade the statutory bar on civil actions against manufacturers and administrators of vaccines for vaccine-related injuries unless a claimant has first filed a timely petition in the Court of Federal Claims.[1]

Plaintiffs' argument, if successful, would contravene the purpose of the Act and would substantially undermine its goals. First, Plaintiffs' position is inconsistent with the plain meaning of "adulterant" and "contaminant." Second, the Secretary has determined that the preservative thimerosal is not an adulterant or contaminant within the meaning of the Vaccine Act, a determination that should be accorded deference under statutory scheme by which vaccine safety and compensation is administered. See Attachment A (Secretary of Health and Human Service's Brief, Geppert v. Secretary of HHS, Court of Federal Claims No. 00-286V (42 U.S.C. § 300aa-

[1] As a practical matter, not all potential claimants included in the broadly defined putative class may come within the Program. Because Plaintiffs have not defined any subclasses, it is difficult to discern those individuals whose claims are not barred. As stated in the Act, however, the Program's bar on civil actions does not apply to putative class members seeking damages for injuries related to vaccines that are not listed as vaccines covered by the Program. In addition, the Act does not require claims against a defendant "chemical manufacturer" of a component of a vaccine to be filed first in the Court of Federal Claims. The Act further excludes claimants who seek individual damages totaling less than $1,000, or any claim for injunctive relief or other non-monetary damages. Nonetheless, as set forth in this Statement of Interest, the Act undeniably prohibits claims against vaccine manufacturers or administrators by putative class members for injuries resulting from vaccines covered by the Program, and those claims should be dismissed.

33(5) was not meant to exclude claims of injury caused by individual components which comprise the vaccine)). As the Secretary is charged with administering the statute and has the delegated authority to regulate presumptively vaccine-related injuries, this Court should defer to the Secretary's interpretation. Should this Court not find the Secretary's interpretation controlling, the doctrine of primary jurisdiction counsels this Court to allow resolution of this technical issue by the Court of Federal Claims -- which is already exercising jurisdiction over more than 60 cases alleging injury from thimerosal -- before ruling on the issue.

## IV. EXPLANATION OF PROGRAM

### A. Program Overview

The Vaccine Program was created in response to two primary concerns: first, the inconsistency, expense, delay, and unpredictability of the tort system in processing and compensating claims of vaccine-injured persons; second, the instability and uncertainty of the childhood vaccine market created by the risks of tort litigation. H.R. Rep. No. 99-908, 99th Cong., 2d Sess. 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6348. Recognizing that "vaccination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken," the Congress acknowledged a responsibility "to ensure that all children who are injured by vaccines have access to sufficient compensation for their injuries." Id. at 6345-6346. Moreover, "[a]n important federal purpose of the Act is to free manufacturers from the specter of large, uncertain tort liability, and thereby . . . keep manufacturers in the market." Schafer v. American Cyanamid Co., 20 F.3d 1, 4 (1st Cir. 1994).

Congress identified several shortcomings in the traditional tort process. For the claimants, "opportunities for redress and restitution are limited, time-consuming, expensive, and often unanswered." H.R. Rep. No. 99-908, 99th Cong., 2d Sess. 4-5 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6347. For the manufacturers, litigation meant increasing expenses and decreasing insurance liability coverage. Id. Congress's solution was to create a "new system for vaccine injury compensation." Id. at 6348. With truncated discovery, presumed injuries, informal procedures, and attorney fee-shifting, this system offered claimants a quicker, and generally more certain, recovery. In turn, by initially diverting litigation to this system, manufacturers were guaranteed a measure of security and could get "a better sense of their potential litigation obligations." Id.

**B. Statutory framework**

Effective October 1, 1988, the Program established procedures through which claimants, or "petitioners," may seek compensation for certain vaccine-related injuries.[2] 42 U.S.C. §§ 300aa-10 to 300aa-34. It established a specialized tribunal of special masters in the U.S. Court of Federal Claims through which vaccine-related injury claims must initially be submitted.[3] 42

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[2] As of January 31, 2002, 6,192 petitions had been filed since the Act's inception; 5,444 of these petitions have been adjudicated. National Vaccine Injury Compensation Program, Monthly Statistics Report, *available at* http://www.hrsa.gov/osp/vicp/monthly.htm. More than $1.3 billion has been paid to approximately 1,700 families and individuals. Id.

[3] *De minimis* claims for less than $1,000 may be brought in civil courts without prior filing under the Vaccine Program. 42 U.S.C.§ 300aa-11(a)(2)(A). The Act mandates, however, that any action seeking an unspecified amount of damages be filed under the Program. Id. Courts have also allowed limited claims for loss of consortium. See Schafer v. American Cyanamid Co., 20 F.3d 1, 7 (1st Cir. 1994). It does not appear from Plaintiffs' allegations that they seek on behalf of themselves and the putative class individual recovery of less than $1,000.

U.S.C. § 300aa-11(a)(1). A key provision at issue in this litigation is the proscription against filing any civil action against a vaccine manufacturer or administrator unless a timely petition is first filed under the Program. 42 U.S.C. § 300aa-11(a)(2)(A); Shalala v. Whitecotton, 514 U.S. 268, 270 (1995)(claimant alleging injury after Act's effective date "must exhaust the Act's procedures" before filing "any *de novo* civil action in state or federal court"). In fact, if potential claimants first seek compensation in state or federal courts, the Act requires that those cases be dismissed regardless of venue. 42 U.S.C. § 300aa-11(a)(2)(B)("If a civil action which is barred under subsection (A) is filed in a State or Federal court, the court shall dismiss the action."). To pursue these claims, individuals must file petitions in the U.S. Court of Federal Claims.

Individual claims[4] are filed by way of a "petition," which must be accompanied by all relevant medical records. Importantly for claimants, the Program is no-fault. 42 U.S.C. § 300aa-11(c). Special masters adjudicate claims according to less adversarial rules that simplify burdens on petitioners. 42 U.S.C. § 300aa-12(d). For instance, the special masters are not bound by common law or statutory rules of evidence. Rules of the Court of Federal Claims (RCFC), Vaccine Rule 8(c). The informal and cooperative exchange of information is the ordinary and preferred practice, and there is no discovery as a matter of right. RCFC, Vaccine Rule 7. Rather,

[4] A proper petitioner is "any person who has sustained a vaccine-related injury," or the legal representative of such person. 42 U.S.C. § 300aa-11(b)(1)(A). Claims must be filed by individuals, and neither the Vaccine Act nor Court of Federal Claims Vaccine Rules authorize filing petitions that, as Plaintiffs attempt to do here, describe a class, group, or category of claimants. Indeed, proceedings that merely define a class or category of claimant, rather than specify a particular individual with an alleged vaccine injury, would frustrate one of Congress's purposes in creating the Act: to allow vaccine manufacturers to get "a better sense of their potential litigation obligations." H.R. Rep. No. 99-908, 99th Cong., 2d Sess. 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6348.

the Program is premised on the notion that the process is "front-loaded" in that all medical records will be filed with the petition. U.S. Court of Federal Claims Office of Special Masters, *Guidelines for Practice under the National Vaccine Injury Compensation Program*, p. 1 ("compensation program is based on the premise that the initial submission -- the petition and accompanying documents -- will essentially contain petitioner's case in chief").

Congress intended the system to be expeditious. H.R. Rep. No. 99-908, 99th Cong., 2d Sess. 12 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6353. Petitions must be filed in the Court of Federal Claims within 36 months after "the date of the occurrence of the first symptom or manifestation of onset" of the alleged vaccine-related injury.[5] 42 U.S.C. § 300aa-16(a)(2). In cases alleging a vaccine-related death, the claim must be filed within 24 months of the death so long as the first symptom of the injury that caused the death occurred not more than 48 months earlier. 42 U.S.C. § 300aa-16(a)(3). Equitable tolling is not available to toll or extend these limitation periods. Brice v. Secretary of HHS, 240 F.3d 1367, 1373-1374 (Fed. Cir. 2001), cert. denied sub nom. Brice v. Thompson, __ U.S. __, 122 S.Ct. 614 (2001).[6]

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[5] Limitations of actions under state law are stayed upon the filing of a petition. 42 U.S.C. § 300aa-16(c).

[6] However, if a claimant improperly files a civil action for a vaccine-related injury in state or federal court rather than in the Court of Federal Claims, the date that action is filed effectively becomes the date the petition is filed . 42 U.S.C. § 300aa-11(a)(2)(B). In that situation, the state or federal court is directed to dismiss the action, but the "date such dismissed action was filed shall . . . be considered the date the petition was filed" in the Court of Federal Claims provided that "the petition was filed within one year of the date of the dismissal of the civil action." Id. Although Plaintiffs purport to include in their putative class all persons receiving vaccines containing thimerosal from 1990 through 2000, some of these claims may be barred by the Vaccine Act's statute of limitations. That determination, however, is required to be made in the first instance by the Court of Federal Claims pursuant to its grant of exclusive jurisdiction under

Currently, the vaccines covered under the Program are diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis B, Haemophilis influenzae type b, varicella, rotavirus, and streptococcus pneumoniae. 42 C.F.R. § 100.3 (2001)(Vaccine Injury Table).[7] The Act defines vaccine-related injuries as follows:

> The term "vaccine-related injury or death" means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition or death associated with an adulterant or contaminant intentionally added to such a vaccine.

42 U.S.C. § 300aa-33(5).

Claimants who suffer injuries according to criteria outlined in the Vaccine Injury Table make out a prima facie case for compensation that the Secretary may rebut only by proving the injury was caused by factors unrelated to the vaccine. 42 U.S.C. §§ 300aa-11(c)(1)(C)(i) and 13(a)(1)(B). Those not suffering a "Table injury" may still obtain compensation by showing by a preponderance of evidence that the injury was caused in fact by the vaccine.[8] Id.

Compensation awarded to a petitioner for a vaccine-related injury may include actual unreimbursable expenses and projected expenses for medical or other remedial care determined to be reasonably necessary; actual and anticipated lost earnings; and actual and projected pain

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the Act, even if those claims are ultimately determined to be time-barred.

[7] Not all vaccines administered to children are covered under the Program. For example, influenza vaccine, which may contain thimerosal, is not a covered vaccine.

[8] The Vaccine Injury Table currently contains nine injuries presumptively related to certain listed vaccines. 42 C.F.R. § 100.3. The Table does not list any injury presumptively linked to thimerosal, and so proof of causation by members of the putative class will be required in the Program, just as in any tort case.

and suffering subject to a statutory cap of $250,000. 42 U.S.C. § 300aa-15(a). Punitive or exemplary damages are prohibited. 42 U.S.C. § 300aa-15(d). In the event of a vaccine-related death, an award of $250,000 is paid to the estate of the deceased. 42 U.S.C. § 300aa-15(a)(2). Reasonable attorneys' fees and other costs are awarded even if the petition is denied, so long as the special master determines that the petition was brought in good faith and there was a reasonable basis for asserting the claim. 42 U.S.C. § 300aa-15(e). Judgments are paid from the Vaccine Injury Compensation Trust Fund, financed by an excise tax on vaccines. 42 U.S.C. § 300aa-15(i)(2); 26 U.S.C. § 9510. Limited review of a decision of the special master is available before a judge in the Court of Federal Claims, and appeals may be taken to the Court of Appeals for the Federal Circuit. 42 U.S.C. § 300aa-12(e), (f).

The Program affords substantial protections to claimants against inordinate delay or awards deemed by the claimant to be inadequate. After first proceeding through the Program, a claimant may reject the special master's judgment for any reason and pursue a traditional tort action in any forum. 42 U.S.C. § 300aa-21(a). Moreover, if the special master fails to issue a decision within the Program's specified time frame of 240 days, exclusive of certain periods of suspension, the petitioner may at that time withdraw from the Program and pursue his or her civil action.[9] 42 U.S.C. § 300aa-21(b).

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[9] Even if petitioners do not have their claims resolved within 240 days (and they can, and, in experience, often do, consent to an extension of this time period) and elect to leave the Program, they may still benefit from participation. For claims filed within the statute of limitations, claimants may begin assembling documents and information necessary to prosecute their claim and may petition the Federal Court of Claims for attorneys' fees and expenses associated with those activities. Although Plaintiffs may argue that this statutorily mandated proceeding merely delays the ultimate filing of the tort case, reimbursed expenses offset any such

In the event a petitioner elects to reject a Program award, the Act places several limitations on subsequent tort remedies. For example, it establishes compliance with Food and Drug Administration ("FDA") requirements as a partial defense for the manufacturer (42 U.S.C. § 300aa-22(b)(2)), and requires tort suits to be tried in three phases (i.e., liability, general damages, and punitive damages). 42 U.S.C. § 300aa-23(a). Generally, compliance with FDA requirements also precludes punitive damages. 42 U.S.C. § 300aa-23(d).

## V. ARGUMENT

### A. Thimerosal is neither an Adulterant or Contaminant within the Plain Meaning of the Act.

The gravamen of the Plaintiffs' case is that thimerosal when used within prescribed limits as a preservative in a licensed vaccine is an "adulterant" or "contaminant" under 42 U.S.C. § 300aa-33(5), and, therefore, injury claims based on this component of the vaccine are beyond the exclusive original jurisdiction of the U. S. Court of Federal Claims. Such an assertion must be denied for at least two compelling reasons. First, the plain meaning of the words "adulterant" and "contaminant" does not apply to thimerosal when, as here, it is used as an ingredient in the approved formulation of a licensed vaccine. Plaintiffs do not allege that the introduction of thimerosal into the specified vaccines was done contrary to an approved and licensed vaccine

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burden from delay.

If thousands of claims are refiled in the Court of Federal Claims as vaccine petitions following dismissal of those claimants from this lawsuit, current administrative resources may be inadequate and other resources may need to be dedicated to resolving these claims in a timely manner. Nevertheless, this potential in no way affects resolution of the jurisdictional issue before this Court.

formulation. Nor can they. Second, based on the available scientific data, FDA has not made any finding to date that even suggests that thimerosal, used as a preservative within the prescribed limits of a licensed vaccine, is an adulterant or a contaminant. By contrast, when asked to do so, FDA declined to order a recall of vaccines containing thimerosal because it found insufficient scientific data to show that the use of thimerosal as a preservative in accordance with approved license formulations renders the drug unsafe or hazardous to the public health.

**1. The plain meaning of "adulterant" and "contaminant" does not encompass thimerosal.**

The cardinal rule of statutory construction is that the court must first look to the plain meaning of the words of a statute to discern the statute's meaning. If that meaning is unambiguous, then the court looks no further. Connecticut Nat'l Bank v. Germain, 503 U.S. 249, 253-54 (1992). Although the words "adulterant" and "contaminant" are not defined in the statute, the plain English definition of an adulterant is "a substance which makes an item impure, spurious, or inferior by adding extraneous or improper ingredients." *The American Heritage College Dictionary* 58 (2d ed. 1992). An "adulterant" is also defined as "[a]n impurity; an additive that is considered to have an undesirable effect or to dilute the active material so as to reduce its therapeutic or monetary value." *Stedman's Medical Dictionary* 30 (27th ed. 2000).

Similarly, a contaminant is "[s]omething that makes impure or corrupt by contact or mixture" (*Webster's 9th New Collegiate Dictionary* 283 (9th ed. 1991)), or "something that causes contamination." *Dorland's Medical Dictionary* 397 (29th ed. 2000). Thimerosal, when used as prescribed in a licensed vaccine formulation, does not fit within any of these definitions. Rather, when used as a preservative, thimerosal acts in precisely the opposite fashion of an

adulterant or contaminant. As a preservative, it deters microbial and fungal growth in order to maintain the safety, purity, and potency of a vaccine.

**2. Thimerosal used within prescribed limits of a valid biologics license is not an adulterant or contaminant.**

Under the Program, an exclusion based on the addition of an adulterant or contaminant extends only to the addition of "foreign" substances or "extraneous" materials. See generally Amendola v. Secretary of HHS, 989 F.2d 1180, 1186 (Fed. Cir. 1993) (stating in dicta that "the only exclusion [from the program] is exposure to a foreign substance introduced into the vaccine itself . . . [T]he exclusion refers only to . . . extraneous material."). When thimerosal is part of a vaccine formulation and added in accordance with the specifications set forth in a valid and effective biologics license, it is neither foreign nor extraneous.

That thimerosal is neither an adulterant or contaminant is further supported by an FDA requirement to use preservatives in products distributed in multi-dose containers, with certain exceptions not relevant here. 21 C.F.R. § 610.15(a). The purpose of adding a preservative is to safeguard against microbial contamination, and thimerosal is effective in that role . *U.S. Pharmacopeia*, (USP 24) 1644 (1999). Thimerosal has been a widely used preservative in vaccines since the 1930s. Statement by William Egan, Ph.D., FDA, before the Committee on Government Reform, U.S. House of Representatives, July 18, 2000.

Plaintiffs contention that thimerosal is an adulterant or contaminant as used vaccines is incongruous with the federal requirement that a vaccine be manufactured according to approved specifications set forth in an effective biologics license. So long as a biologics license is in effect and FDA has not found that thimerosal is unsafe as used in such licensed products, thimerosal used as prescribed cannot, and should not, be considered an adulterant or contaminant under the

Vaccine Act.

FDA has found no grounds upon which to order a recall of vaccines containing thimerosal as a preservative or to revoke or suspend the approved licenses for such vaccines. A biologics license is valid until revoked or suspended. 21 C.F.R. § 601.4(a). A biologics license may be revoked if FDA finds, among other things, that the product is not safe and effective for all of its intended uses. 21 C.F.R. § 601.5(b)(1)(vi). A biologics license may be suspended if FDA finds that there is ground for revocation and there is a danger to public health. 21 C.F.R. § 601.6(a). FDA has not revoked or suspended any vaccine license on the ground that it contains the preservative thimerosal in accordance with an approved biologics licensing agreement. FDA may also order the recall of a vaccine upon a determination that the product presents an imminent or substantial hazard to the public health. 42 U.S.C. § 262(d)(1). FDA was asked to recall vaccines containing thimerosal, and, in response, FDA stated that these vaccines did not violate FDA law and that there was insufficient information to support a recall. FDA letter to Safe Minds, November 13, 2001 (Attachment B).

**3. The legislative history supports the finding that Congress intended that injuries allegedly related to thimerosal be brought under the Program.**

The use of preservatives in vaccines is not new. In fact, thimerosal has been added to vaccines since the 1930s. Accordingly, when Congress created the Program it chose to cover many vaccines that already contained thimerosal. Given the congressional purpose of channeling liability for vaccine injuries to the Program and the fact that vaccines chosen for coverage contained thimerosal, it is incongruous to argue that at the same time Congress extended coverage to these vaccines, it intended to define away that coverage for any injury related to thimerosal. The reasonable conclusion, bolstered by FDA treatment of preservatives as

"constituents" of vaccines, is that preservatives were considered part and parcel of the vaccines covered under the Program. See 21 C.F.R. § 615 (providing that constituents include preservatives).

Indeed, while there is no legislative history directly bearing on the proper interpretation of "adulterant" or "contaminant," there is legislative history revealing a general congressional intent to cover injuries related to vaccine components such as preservatives. In this regard, one vaccine covered by the Program, inactivated polio vaccine, contains trace amounts of antibiotics left over from the production process. Congress was aware that these materials were in this vaccine.

> No serious side effects of currently available IPV [inactivated polio vaccine] have been documented. The preparation contains trace amounts of streptomycin and neomycin and should not be given to individuals who have a hypersensitivity reaction to these antibiotics.

House Comm. on Energy and Commerce, 99th Cong., 2d Sess., *Childhood Immunizations*, p. 32 (Comm. Print 99LL 1986). Rather than excluding injuries related to the antibiotics, Congress made those injuries presumptively vaccine-related. The Vaccine Injury Table Congress created lists anaphylaxis and anaphylactic shock -- hypersensitivity reactions -- as injuries presumptively related to receipt of inactivated polio vaccine. 42 U.S.C. § 300aa-14(a)IV.

### B. Interpreting Thimerosal as an "Adulterant or Contaminant" Undercuts the Comprehensive Regulatory Scheme Established by Congress to Both Promote the Public Health by Ensuring the Vaccine Supply and Compensate Vaccine -Related Injuries.

Even if the phrases "adulterant" and "contaminant" were ambiguous in isolation, that ambiguity quickly vanishes upon examining the words as part of "a symmetrical and coherent regulatory regime." Food and Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000). "It is a fundamental canon of statutory construction that the words of a statute

must be read in their context and with a view to their place in the overall statutory scheme." Davis v. Michigan Dep't of Treasury, 489 U.S. 803, 809 (1989).

Courts have, in fact, found this interpretive approach essential to construe provisions of the Act. "When the legislative purpose is incorporated in a complex piece of legislation, such as those establishing a major regulatory or entitlement program, the meaning of any particular phrase or provision cannot be securely known simply by taking the words out of context and treating them as self-evident." Amendola, 989 F.2d at 1182. Examining the words "adulterant" and "contaminant" as part of a comprehensive regulatory scheme designed to filter injury claims associated with certain vaccines through the Program compels the conclusion that these words were not meant to include thimerosal used as a licensed vaccine preservative.

First, the Act unambiguously discourages state law-based tort actions by raising hurdles to the pursuit of such claims for those who elect to reject the Program-derived result. For example, in such situations covered vaccine manufacturers generally have a complete defense to liability based on "failure to warn" if they have "complied in all material respects with all requirements under the Food, Drug, and Cosmetic Act and Section 351 of the Public Health Service Act." 42 U.S.C. § 300aa-22(b). To overcome this defense, a plaintiff must demonstrate by "clear and convincing evidence that the manufacturer failed to exercise due care" or otherwise engaged in fraudulent or criminal activity. 42 U.S.C. § 300aa-22(b)(2). This careful reshaping of state tort law evinces the statutory purpose of keeping the vast majority of injury claims associated with vaccines in the Court of Federal Claims. "Congress' purpose is both clear and clearly evidenced by the statutory framework. The statute provides a strong bias in favor of bypassing the civil litigation route in favor of compensation claims under the Act." Amendola, 989 F.2d at 1184.

The availability of the regulatory compliance defense lends further support for the finding that thimerosal is not an "adulterant or contaminant." FDA regulations require the use of a preservative in certain vaccines to inhibit microbial contamination, and the agency licensed vaccines using thimerosal in that role. It does not follow that Congress would provide a regulatory compliance defense -- based on compliance with regulations designed to ensure the safety of vaccines -- to manufacturers who achieve compliance, in part, by intentionally adding a purported "adulterant" or "contaminant" to otherwise safe vaccines. See Amendola, 989 F.2d at 1182 (stating that in interpreting the Vaccine Injury Compensation Act, "provisions *in pari materia* must be construed together.").

Congress chose not to preempt all state tort actions.[10] Still, its detailed establishment of a specialized tribunal to hear vaccine-related claims and its deliberate reshaping of state tort law demonstrate an overriding purpose that vaccine-related injury claims "associated with one or more of the vaccines set forth in the Vaccine Injury Table" be first brought under its Vaccine Program where statutorily prescribed benefits and burdens are divided between claimants and defendants. 42 U.S.C. § 300aa-33(5). Both substantive and procedural provisions of the legislation underscore carefully crafted legislative compromises on many fronts. Substantively, the Act dispenses with any requirement of proving negligence. 42 U.S.C. § 300aa-11. Procedurally, proceedings before the special masters are more flexible in admissibility of evidence and encourage a less adversarial procedure. 42 U.S.C. § 300aa-12(d)(2). These and the

[10] In fact, a provision of the Act proscribes states from passing laws that prohibit suits against vaccine manufacturers not otherwise barred by the Act. 42 U.S.C. § 300aa-22(e).

Act's many other detailed provisions[11] leave little doubt that the statute was deliberately designed to balance the goals of protecting the viability of the vaccine supply and compensating individuals for injuries arising from routine vaccinations. *See* H.R. No. 99-908, 99th Cong., 2d Sess. 6, *reprinted in* 1986 U.S.C.C.A.N. at 6347 (stating that, "but for the relatively few who are injured by vaccine -- through no fault of their own -- the opportunities for redress and restitution are limited, time-consuming, expensive, and often unanswered.").

Introducing uncertainty into the delicate balance reached by Congress by allowing state tort liability, absent the filter of the Act, could have dramatic effects that substantially undermine Congress's objectives and have deleterious effects on the public health. Such exposure may prompt increases in vaccine prices, or otherwise adversely effect vaccine supply and use. American Cyanamid, 20 F.3d at 4. Because of the overriding importance to the public health, Congress established a successful, comprehensive procedure which facilitates compensation to those injured while protecting the nation's vaccine supply. This Court should uphold that procedure by denying Plaintiffs' Motion to Remand and dismissing those claims falling within the purview of the Vaccine Program.[12]

### C. This Court Should Defer to the Agency's Interpretation Excluding Thimerosal from the Meaning of Adulterant or Contaminant, or at Least

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[11] Also among the Act's provisions are detailed rules as to the weight of evidence (42 U.S.C. §300aa-13), types and amounts of compensation (42 U.S.C. § 300aa-15), attorney's fees (42 U.S.C. § 300aa-15(e)), and timelines for both the issuance and the rejection of special masters' judgments (42 U.S.C. §§ 300aa-12(g), 300aa–21(a)).

[12] *See* Daniel Ridgway, "No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program," 24 *Journ. of Health Politics, Policy and Law* 59, 76 (1999) (discussing the relative success of the program in keeping vaccine prices low, supplies at optimums, and manufacturers in the market and innovating, as well as the increase in vaccination coverage since the passage of the Act).

**Defer Determination of the Issue until the Court of Federal Claims Resolves this Technical Issue.**

In this Circuit, agency constructions of their own statutes are controlling unless plainly erroneous. Naveillier v. Sletten, 262 F.3d 923, 945 (9th Cir. 2001)(citing Auer v. Robbins, 519 U.S. 452, 461-63 (1997 )).[13] Although no specific authority has been granted to regulate what constitutes an "adulterant" or "contaminant" under section 33(5), the broad delegation of authority to the Secretary to administer the Program counsels that deference be given to the Secretary's interpretation of Program terms. Indeed, the delegation concerns the very topic defined by section 33(5), "vaccine-related injuries or death." Thus, the Secretary's consistent interpretation that any injury claims allegedly caused by thimerosal in covered vaccines are "vaccine related" and should therefore be adjudicated through the Court of Federal Claims is entitled to deference.[14]

Indeed, the statutory scheme embodied in the Program also dictates deference. Congress delegated the broad power to add, delete, or, in essence, redefine injuries on the Vaccine Injury Table to the Secretary. 42 U.S.C. § 300aa-14(c)(3); see O'Connell v. Shalala, 79 F.3d 170, 177 (1st Cir. 1996) ("[T]he brute power to subtract listed medical conditions from the Table

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[13] See also Carson Harbor Village v. Unocal Corp., 270 F.3d 863, 877 n.5 (9th Cir. 2001) ("Although we would normally address the agency's interpretation of the statute . . . here there is no EPA determination as a point of reference or deference.")(citation omitted).

[14] See Attachment A at 2: Respondent's Brief interpreting 42 U.S.C. § 300aa-33(5), Geppert v. Secretary of HHS, No. 00-286V (the adulterant and contaminant exception "was not meant to exclude claims of injury caused by individual components which comprise the vaccine itself."). See also National Vaccine Injury Compensation Program web-page, *available at* <http://www.hrsa.gov/osp/vicp/qanda.htm> ("Because thimerosal is not an adulterant or contaminant, individuals who have claims relating to thimerosal in vaccines covered under the VICP . . . must first file the claim with the VICP before pursuing any other civil litigation."). The Secretary did not agree in Geppert that the injury alleged resulted from thimerosal.

encompasses the more modest power to trim the definitions associated with listed medical conditions."). This manifests congressional recognition of the Secretary's expertise in assessing harms potentially related to vaccines. Though the Secretary's interpretation is proffered to this Court in the form of this Statement of Interest, it should be no less controlling since it represents "the agency's fair and considered judgement on the matter in question." Auer v. Robbins, 519 U.S. 452, 462 (1997).[15] Cf. Geier v. American Honda, 529 U.S. 861, __, 120 S.Ct. 1913, 1926-27 (2000)(In construing federal preemption of state tort law under National Traffic and Motor Vehicle Safety Act, Court placing "some weight" on Department of Transportation's amicus brief due to: the delegated authority to implement the statute, the technical nature of the subject matter, the consistency of the agency's interpretation, and the extensive and complex history of the issue. "In these circumstances, the agency's own views should make a difference.")(citing Auer)(other citations omitted).

The Court of Federal Claims, charged with resolving petitions under the Program, has effectively endorsed the Secretary's position on how "vaccine-related injury or death" must be defined. Order, Geppert v. Secretary of HHS, No. 00-286V (Fed. Cl. Sp. Mstr. Oct. 12, 2001). The special master's order did not explicitly resolve the definition of "adulterant" or "contaminant"; rather, noting the petitioner's "acquiesce[nce]" and the lack of "contest" by the

[15] See United States v. Mead Corp., 533 U.S. 218, __, 121 S. Ct. 2164, 2172-3 (2001) ("We have recognized a very good indicator of delegation meriting *Chevron* treatment in express congressional authorizations to engage in the process of rulemaking . . . . *The want of procedure here does not decide the case, for we have sometimes found reasons for Chevron deference even when no such administrative formality was required and none was afforded.*")(italics added). This Statement of Interest is certainly sufficient to rebut Plaintiffs' unsupported claim that the Secretary has refused to challenge the Court's jurisdiction to adjudicate their claims either on an individual or class-wide basis.

Government,[16] the special master continued proceedings in the case. However, it is the duty of the court to determine jurisdiction over proceedings. Fincke v. United States, 675 F.2d 289, 297 (Fed. Cl. 1982). It cannot be gained merely by the consent of the parties. City of Kenosha v. Bruno, 412 U.S. 507, 511 (1973). In allowing the suit to continue in the Court of Federal Claims, the special master implicitly construed "adulterant" and "contaminant" to exclude thimerosal-related vaccine injury claims. Cf., id. at 511-513 (on its own motion, the Court interpreted a statutory term as to reject the assertion of jurisdiction).

Even if this Court were hesitant to accord the Secretary's interpretation controlling weight, it should first allow full consideration of the issue in the Court of Federal Claims where jurisdiction has already been assumed. In this regard, the principles underlying the doctrine of primary jurisdiction are instructive and counsel that the question of whether thimerosal is an adulterant or contaminant under the Act be resolved in the first instance by the body created by the Act specifically to decide legal questions arising from its provisions. Invocation of primary jurisdiction is appropriate when the subject of court litigation "is . . . at least *arguably* protected or prohibited by . . . [a] regulatory statute." Ricci v. Chicago Mercantile Exchange, 409 U.S. 289, 299-300 (1973) (emphasis added); see Reiter v. Cooper, 507 U.S. 258, 268 (1993) (explaining primary jurisdiction and reaffirming Ricci). The Act requires that all litigation subject to its jurisdiction be initially brought at the Court of Federal Claims, making that entity analogous to an agency with primary decisionmaking authority over matters "arguably" regulated by the Act. Although subject to "no fixed formula," a court should defer to the primary

[16] The Government's position was more than the lack of "contest" to the special master's jurisdiction. The brief affirmatively asserted that "the components added to the microorganisms to create vaccines cannot be considered adulterants or contaminants." Attachment A at 3-4.

jurisdiction of an agency when: (1) the agency's specialized expertise makes it a preferable forum for resolving the issue; (2) there exists a strong need for uniform resolution of the issue; and, (3) there is a potential that judicial resolution of the issue will have an adverse impact on the agency's performance of its regulatory responsibilities. 1 K. Davis and R. Pierce, *Administrative Law Treatise* § 14.1 (3rd ed. 1994).

All of these considerations arise here. First, the Court of Federal Claims has specialized expertise regarding legal and technical issues arising under the Act as it is the adjudicatory entity specifically tapped by Congress to resolve them. 42 U.S.C. § 300aa-12(c), (d). Second, uniform resolution is demanded. By the Act's express terms, federal law admits of no concurrent jurisdiction over these thimerosal claims; they either must, or cannot, be pursued under the Act, depending on whether the exception under section 33(5) is operative. By resolving this issue initially in the Court of Federal Claims, legally conflicting decisions among the federal and state courts may be avoided. Finally, the adverse impact is substantial in that a vast number of claims that must otherwise be brought in the Court of Federal Claims would evade its jurisdiction. Indeed, Congress established the Program to overcome precisely the problems associated with multiple, potentially conflicting judicial rulings that might adversely affect the willingness of manufacturers or administrators to produce or provide needed vaccines or impede the reasonably expeditious and consistent review of claims by those individuals injured through the receipt of mandatory vaccinations.

## VI. CONCLUSION

For the reasons set forth in this Statement of Interest, Plaintiffs' Motion to Remand should be denied and their complaint should be dismissed against the defendant vaccine manufacturers and administrators to the extent that the putative class members seek damages for

injuries resulting from vaccines covered by the Program. Plaintiffs cannot avoid the exclusive jurisdiction of the Court of Federal Claims and the procedures of the Program by erroneously arguing that thimerosal is an adulterant or contaminant. The plain language of the statute and the determinations that have been made by the Secretary demonstrate that their argument is fundamentally incorrect and without merit.

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